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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|-----------------------|---------------------|------------------|
| 10/694,075 | 10/27/2003 | Ekambar R. Kandimalla | HYB-005US6 | 3779 |
| 7590 WAYNE A. KEOWN SUITE 1200 500 WEST CUMMINGS PARK WOBURN, MA 01801 | | | | |
| 09/14/2010 | | | | |
| EXAMINER | | | | |
| HORNING, MICHELLE S | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1648 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/694,075

Applicant(s)

KANDIMALLA ET AL.

Examiner

MICHELLE HORNING

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2010 and 23 July 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/GS/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This action is responsive to communication filed 6/16/2010 and 7/23/2010.

Claim 25 is under current examination.

Note that this application has been transferred to another examiner and all future correspondences regarding this application should be directed to Michelle Horning of AU1648.

Any rejection(s) not reiterated herein has been withdrawn.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/23/2010 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 25 is rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5599797 (hereinafter as “Cook”; see form 892) as further evidenced by the instant specification and Stein and Cheng (*Science*, 1993; see form 892).

The claim is directed to (in part): a method for modulating the immunostimulatory effect of an immunostimulatory oligonucleotide compound, comprising introducing into the oligonucleotide a 1',2'-dideoxyribose.

Cook discloses a method for modulating the immunostimulatory effect of an oligonucleotide comprising introducing a phosphorothioate into the oligonucleotide for the purposes of exhibiting resistance to nucleases (col. 2, lines 54+); this meets the single method step of introducing a 1',2'-dideoxyribose into the oligonucleotide of instant claim 25 (further discussed below). In addition, the author teaches that an unmodified "wild-type" oligonucleotide is not useful as a therapeutic agent because they are rapidly degraded by nucleases (col. 2, lines 44+). Thus, modifying the structure of a sequence via the insertion of 1',2'-dideoxyribose leads to *modulation of the immunostimulatory effect of an immunostimulatory oligonucleotide compound*, or therapeutic agent, given that the modified oligonucleotide is not readily degraded; in contrast, the unmodified sequence would be degraded, losing its structural integrity and as a result, its function.

Note that the introduction of phosphorothioates meets the definition of an "immunostimulatory moiety" as defined by the instant specification [0066]. The definition provides that an immunostimulatory moiety is a structure that causes the immunostimulatory oligonucleotide to be more immunostimulatory than it would be in the absence of the immunostimulatory moiety. The phosphorothioate-containing oligonucleotide is more immunostimulatory in that the phosphorothioate would lead to a nuclease-resistant structure allowing it to perform its structure-dependent

immunostimulatory function as opposed to one lacking the phosphorothioate which would lead to nuclease-dependent degradation.

It is also noted that any structural change in a compound would inherently lead to a change in the compound's function because there is a structure to function correlation.

See Figures 1-3 of the instant specification which provide the structure of 1', 2'-dideoxyribose. The instant specification describes 1',2'-dideoxyribose as sugar modification *in a nucleoside*; see para. [0067].

The reference by Stein and Cheng is only cited to provide further evidence of the phosphorothioate linkage structure (1',2'-dideoxyribose) shown in Fig. 1.

Thus, the prior art anticipates the claimed invention.

Conclusion

No claim is allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELLE HORNING whose telephone number is (571)272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ZACHARIAH LUCAS can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. H./
Examiner, Art Unit 1648

/Zachariah Lucas/
Supervisory Patent Examiner, Art Unit 1648